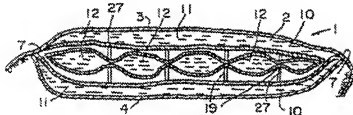




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>6</sup> : A61F 7/00</p>	<p>A1</p>	<p>(11) International Publication Number: <b>WO 00/03667</b>  (43) International Publication Date: 27 January 2000 (27.01.00)</p>
<p>(21) International Application Number: PCT/US99/16251  (22) International Filing Date: 16 July 1999 (16.07.99)  (30) Priority Data: 09/118,488 17 July 1998 (17.07.98) US  (71)(72) Applicant and Inventor: DER OVANESIAN, Mary [US/US]; - (US).  (74) Agent: CROSBY, Kevin, P.; Main, Haley, DiMaggio &amp; Crosby, P.A., Suite 1609, 1 E. Broward Boulevard, Fort Lauderdale, FL 33301 (US).</p>	<p>(81) Designated States: AB, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report.</i></p>	

(54) Title: HOT OR COLD PAD WITH INNER ELEMENT



## (57) Abstract

A flexible heat transfer device for heating or cooling a surface such as the skin has an envelope (2) formed from two sheets. The envelope contains a high thermal capacity first material (11) such as a freezing gel that is flexible when frozen for good surface contact. A pouch (24) within the envelope contains a high thermal capacity second material (12) that may have different physical properties than the first material. The pouch may be segmented, or there may be multiple pouches. The device is more versatile in its applications and provides for more prolonged heating and cooling. The pouch may be in two parts within a frangible partition (154) that generates heat or cold when the partition is ruptured and the two parts mixed.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HB	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LJ	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## HOT OR COLD PAD WITH INNER ELEMENT

## TECHNICAL FIELD

5 This invention relates to the field of therapeutic devices which may be reusable and which may be used for cooling or heating and features a flexible bag which may be heated or cooled and then applied to a body part for thermal application with an inner element that enhances the thermal effects.

## BACKGROUND ART

10 U.S. Patent No. 4,592,358 issued June 30, 1986, to Westplate provides a useful review of the patent literature in this art.

Despite the numerous advances that have been made in this art, people who need to apply heat or cold to the body for prolonged periods of time still find deficiencies in the available devices, because they don't provide relatively uniform temperature for relatively long periods of time, with the exception of the electric heating pads. When heat or cold is to be applied to the body surface, the temperature must not be so hot or cold as to be injurious or uncomfortable, while the total thermal capacity must be great enough to be therapeutically effective for a prolonged period of time.

## DISCLOSURE OF INVENTION

25 The invention comprises a flexible, conformable hot or cold pack having an envelope of a first high heat capacity material surrounding a pouch or other receptacle or receptacles containing a second high heat capacity material for enhanced and more prolonged application of heating or cooling to any surface.

30 The envelope and inner pouch are impervious to the materials being held within them. For this reason, the material stored in the envelope does not mix with the material within the inner pouch. By placing a material in the envelope having a different thermal capacity than the material within the pouch, and by selecting material which changes phase at a predetermined temperature so as to maximize the heat transfer characteristics of the effective device, the effective duration of the heat transfer is lengthened

without exposing the surface to the extreme temperature of the material in the inner pouch.

5 The invention also encompasses embodiments wherein the inner pouch is anchored to the envelope. By anchoring the inner pouch, the inner pouch remains essentially centered in the envelope and which causes the device to transfer heat evenly regardless of how it is applied to the surface.

10 The invention also includes embodiments which incorporate an air bladder. The air bladder functions as a cushion and as an insulator that moderates the amount of heat being transferred.

The invention also includes embodiments wherein the device has an insulator other than or in addition to an air bladder on its exterior. The insulator can be utilized to moderate the amount of heat being transferred. The insulator can also be located distal  
15 the surface with which heat is to be exchanged in order to prevent an inefficient or undesired rate of heat transfer away from said surface.

The invention also includes a bandage that is capable of transferring heat. The bandage is typical of bandages in that it  
20 attaches to a surface (the skin) to provide a sanitized cover to a wound. The bandage of the invention also includes a means for transferring heat to the wound in order to sooth the wound and facilitate healing, and prevent swelling.

25 The invention also includes means of attaching the device to a patient. The means include but are not limited to belts and straps that can be wrapped around the surface in order to hold the device against the surface.

The invention also includes chemical compositions usable as materials that are held within the envelope and the inner pouch.  
30 These materials have high heat capacities, leak protection, and decreased toxicity.

The invention also encompasses embodiments that are shaped so they can transfer heat with the objects that they hold. For example, the device could be shaped like a bowl, a cup, or a  
35 bottle. The device could also be shaped like a piece of clothing: for instance, a shirt, a cap, a mask, a shoe, a belt, or a sock.

These advantages and features of the invention will become more apparent when the detailed description is studied in

conjunction with the drawings, in which like elements are designated by the same reference characters in the various figures.

#### BRIEF DESCRIPTION OF DRAWINGS

5        Figure 1 is a perspective view of the invention with a removable refrigerant pouch ready to be inserted.

      Figure 2 is a sectional view taken through line 2-2 of Figure 1 with pouch inserted.

10       Figure 3 is a sectional view, as in Figure 2, of another embodiment of the invention with a non-removable inner high thermal capacity material.

      Figure 4 is a sectional view, as in Figure 2, of another embodiment of the invention with reversible inner and outer high thermal capacity materials.

15       Figure 5 is a sectional view of the embodiment of Figure 4 partially everted.

      Figure 6 is a sectional view of the embodiment of Figure 4 completely everted.

20       Figure 7 is a sectional view taken through line 7-7 of Figure 1.

      Figure 8 is a top plan view of another embodiment of the pad of the invention.

      Figure 9 is a sectional view taken through line 9-9 of Figure 8.

25       Figure 10 is a sectional view of yet another embodiment of the invention.

      Figure 11 is a sectional view of still another embodiment of the invention.

30       Figure 12 is a top plan view of another embodiment of the invention.

      Figure 13 is a sectional view taken through line 13-13 of Figure 12.

      Figure 14 is a sectional view of another embodiment of the invention.

35       Figure 15 is a top view of an embodiment having an air bladder.

      Figure 16 is a side, cross-sectional view made along the line 16 shown in figure 15.

Figure 17 is a top view of an embodiment having an air bladder and insulator.

Figure 18 is a side, cross-sectional view made along line 18 in Figure 17.

5 Figure 19 is a side-cross sectional view made alone line 19 shown in Figure 20.

Figure 20 is a bottom view of the bandage shown in Figure 19.

Figure 21 is front view of an embodiment containing holes and a belt to attach the device to a surface.

10 Figure 22 is a cut-away, perspective view of a cylindrically shaped pack.

Figure 23 is a top view of a pad having a plurality of envelopes connected with webs.

15 Figure 24 is a front, cross-sectional view along line 24 shown in Figure 23.

#### BEST MODE FOR CARRYING OUT THE INVENTION

Referring now first to Figures 1, 2 and 7, the embodiment of the invention shown here comprises flexible heat transfer device 1 that conforms readily to the irregular surface of a body part so as to provide good surface contact for effective thermal transfer for heating or cooling. End straps 22 with hook and loop fasteners 23 permit the device to be wrapped around an arm, for example, and secured in place by the straps. Device 1 includes 25 outer envelope 2 formed of two double-walled sheets 3, 4 having broad outer faces 5. Faces 5 roughly divide the outer portion of envelope 2 into two halves. Sheets 3, 4 are joined together on three of their mutual edges 7 and unjoined on one mutual edge 6. Each double-walled sheet 3, 4 is formed of inner panel 8 and outer 30 panel 9 sealed along all their edges 6, 7 to define therebetween volume 10. Volumes 10 contain first high thermal capacity material 11 such as one of the freezing gels well known in the art. Examples of such freezing gels are described within U.S. Patent 4,324,111; these freeze gels change state from liquid to slush at 35 around zero degrees centigrade (0° c) and require considerable heat energy as it warms through this change of state to serve as an artificial ice that is not rigid. U.S. Patent 5,314,005 discusses

other materials for this purpose including some that may be heated in a microwave oven for use as hot packs.

Envelope 2 so formed is open at edge 6 to permit the insertion of a flexible pouch 24. Pouch 24 and the envelope are formed of thin flexible liquid-impermeable web such as plastic film. The thickness shown in the figures has been exaggerated for illustrative purposes.

Pouch 24 contains second high thermal capacity material 12. After inserting pouch 24 through open side 6 of envelope 2 into space 13 defined by inner panels 8, open side 6 may be closed by releasable closure 25 which may be hook and loop, snaps, zipper, or the like.

Multiple pouches 24 may be provided so that one can be used in envelope 2 while others are being chilled or heated.

Pouch 24 may be segmented as shown to make it more flexible and to maintain a flatter shape for insertion in the envelope by seams 19 sealing together two flexible webs 14 that make up the outer wall of pouch 24. Seams 19 may be provided with notches 26 that cooperate with short partitions 27 connecting the inner panels 8. This stabilizes pouch 24 within envelope 2.

High thermal capacity material 12 in pouch 24 may be identical to, or different from, material 11 in volume 10 of envelope 2. By being segmented, pouch 24 can remain flexible at seams 19 even if high thermal capacity material 12 is rigid and/or frozen. For example, if material 12 is frozen water, pouch 24 remains flexible at seams 19.

Materials 11 and 12 may be selected on the basis of their particular physical properties to enhance the utility of device 1. Those properties include, but are not limited to, heat of fusion, heat capacity, thermal conductivity, temperature of transition from liquid to solid (melting point), rigidity in the solid phase, reaction to microwave radiation, vapor pressure, and boiling point.

The term "high thermal capacity material" is used herein to refer to a material such as water, a freezing gel, or materials disclosed in the U.S. Patents 5,314,005; 4,592,358; 4,324,111 (the disclosures of all three of which are incorporated herein by reference as though fully set forth herein) that have a high heat of fusion and/or a high heat capacity such that a relatively large

number of calories is required to change the temperature thereof compared to most materials. The principal ingredient in most of these high thermal capacity materials is water. Water's heat of fusion, that is the amount of heat given up when going from liquid to solid or absorbed when going from solid to liquid, is eighty calories per gram (80 cal/g). The heat of fusion of water is more than triple that of most materials. The heat capacity of water, that is the amount of heat given up or absorbed to change its temperature one degree centigrade (1°C) is one calorie per gram (1 cal/g). The heat capacity of water is more than triple that of most materials. Preferred high thermal capacity materials 12 have a heat of fusion and/or a heat capacity that is at least one half that of water.

High thermal capacity materials 11, 12 containing water have been found to be particularly suitable for use with hot and cold applicators such as those described herein because water has an excellent heat capacity and density. Consequently, by choosing a composition that undergoes a change of phase at a predetermined, desired temperature, material 11, 12 is able to transfer a significant quantity of heat regardless of whether device 1 is being used as a hot or cold pad. Accordingly, material 11, 12 preferably is chosen to be one that undergoes a phase change while being recharged such that it will also go through the reverse phase change at the desired temperature when being used to heat or cool a surface.

Materials 11 and 12 in an alternate embodiment can be a non-aqueous material. Examples, of non-aqueous materials include but are not limited to mineral oil and natural oils. These non-aqueous materials can have freezing points below zero degrees centigrade (0° C).

Materials 11 and 12 can be base upon aqueous fluids that can contain a freezing point depressant as described below. The water can be of any suitable type, including tap water, purified, distilled, or de-ionized water. Preferably, suitable materials are added to the aqueous liquid to form a gel. Any suitable proportions can be used which form a gel of suitable viscosity and other properties in the operable temperature ranges. The 3M Company of St. Paul, MN markets a gel pack under the trademark



"COLD COMFORT" which contains a gel made from seventy weight percent (70%) water, twenty-four weight percent (24%) propylene glycol, and five weight percent (5%) hydroxypropyl methylcellulose. While this composition is specifically included, other percentages of the materials are also to be considered. A water soluble polymer can be wetted with a wetting agent, then mixed with the aqueous liquid to form a gel. Any suitable combination of materials can be used, provided that the gel that is formed has the necessary heat capacity and heat transfer rate.

The water soluble polymer can be a natural polymer such as a natural gum, cellulosic polymer, or animal polymer such as gelatin, or a synesthetic polymer. The polymer can be acrylic such as acrylic acid and methacrylic acid, acrylamide, and acrylonitrile. The polymer can be a cellulose polymer including cellulose and lignocellulose. Natural gums that can be used include guar gum, gum tragacanth, locust bean gum, and Xanthan gum.

A preferred family of synthetic water-soluble polymers based upon acrylic and methacrylic acids, wither as homopolymers or copolymers including suitable comonomer such as acrylamide, acrylonitrile and the like. Many acrylic polymers absorb water readily. U.S. Patent No. 5,534,020 discloses a "crosslinked modified acrylic polymer" which is available commercially from JRM Chemicals, Inc. as "SOIL MYST HYDRO"(TM). Copolymers of glucopyranose and polyethylene glycol are available commercially under the trademarks "Liporamnosan" and "Idroramnosan" from Tri-K Industries. "SGP" brand absorbent polymer is a hydrolyzed starch-polyacrylonitrile graft copolymer available from the Granin Processing Corp. of Muscatine, IA. "Superabsorbent" acrylic polymers are disclosed in U.S. Patent 5,843,145 and are available from Stockhause, Inc. of Greensboro, NC and Nalco Chemical Co. of Naperville, IL. The Stockhause version is a crosslinked homopolymer of partially neutralized acrylic acid.

To form a gel from these polymers, a wetting agent should be included to thoroughly wet the polymer before combining it with water. Suitable wetting agents include alcohols, which can be polyhydric or monohydric alcohols, such as ethylene glycol, propylene glycol, glycerine, methanol, ethanol, propanol and the like. In forming a gel, the polymer typically is crosslinked,

which can be done using crosslinking agent such as polyvalence metal cations or organic crosslinking agents such as divinylbenzene. Suitable mixing apparatus can be used, as disclosed in U.S. Patent No. 5,843,145, which is incorporated herein by reference. When the viscosity properties of the gel are too low, thickening agents such as trisaminothane, sodium hydroxide, and corn starch can be used to increase the viscosity.

Various water-soluble organic compounds can be used in aqueous liquids or gels as freezing point depressants. Included are water-soluble monohydric alcohols and their derivatives, such as methanol, ethanol, and isopropyl alcohol; water-soluble polyhydric alcohols such as ethylene glycol, propylene glycol, 1-3-propylene glycol, glycerin, and 2-methyl-2,4-pentanediol; and other water-soluble organic compounds such as acetone, dimethylsulfoxide, methylsulfonic acid, ethylsulfonic acid, diethylamine, methylamine, and formic acid. Other suitable compounds include monosaccharides, such as erythritol, arabinose, xylose, xylitol, glucose, glucitol (sorbitol or sorbite), gluconic acid, glucuronic acid, glucaric acid, galacturonic and water-soluble polysaccharide such as agarose, amylose, sodium alginate, glycogen, chondroitin, chondroitin sulfuric acid, dextran, pectic acid, propylene glycol alginate, pullulan, and chondroitin sodium sulfate.

As for materials 11 and 12 which are permitted to freeze, the disclosure can be based upon the above, with the proviso that a gel need not be formed and the limitation of being non rigid at zero degrees celsius (0° c) need not be met. In fact, this material, contained in the inner container, preferably freezes completely, so as to be capable of absorbing a maximum amount of heat in thawing and warming up to ambient temperature. Similar aqueous fluids, agents if necessary to form a gel can be employed. Although a simple aqueous fluid, with or without freezing depressants would provide the desired thermal properties, a gel that minimizes leakage may still be desirable.

With regard to the composition of the gel, the following U.S. patents are incorporated by reference: 4,273,667; 3,545,230; and 5,843,145.

Insulation such as foam is comprised mostly of trapped air which has a low thermal conductivity, i.e. it transmits calories

poorly. Because it is a gas, air has very low density (g/cc). Consequently, air has very low thermal capacity per volume of insulation.

Thermal conductivity of the material 11, 12 is important in the rate of transfer of heat to or from pouch 24. By acting as a partial insulator, material 11, 12 can prolong the cooling effect and also prevent a very cold or hot insert from injuring the skin, while maintaining a relatively uniform surface temperature.

Envelope 2 may also be used without pouch 24, as desired.

Referring now to Figure 3, heat transfer device 1 is shown in which two double-walled sheets 3, 4 are sealed on all edges 6, 7 with sealed inner space 13 defined by the two inner panels 8 containing second high thermal capacity material 12 and the volumes between the double walls of each sheet containing first high thermal capacity material 11.

Figures 4-6 show another embodiment of the invention in which the entire device may be turned inside out like a reversible jacket. As shown in the first mode of operation in Figure 4, device 1 is formed of two double walled sheets 3, 4 that contain in volumes 10 between outer panels 9 and inner panels 8 first high thermal capacity material 11. Sheets 3, 4 are sealed on three edges 7 and not sealed on edge 6. The space between sheets 3, 4 is divided into three compartments by two webs 14. Each web 14 is sealed on all its edges to one of the other inner panels 8 to define therebetween sealed compartment 15 containing therein second high thermal capacity material 12. Third compartment 16 defined by two webs 14 which are open at the edge 6, and are empty.

As shown in Figures 5 and 6, envelope 2 may be everted or turned inside out to the configuration of Figure 6 in which second material 12 is on the outside enveloping first material 11 on the inside. This embodiment may be useful when the different physical properties of materials 11 and 12 may be more useful on the outside for certain applications, making a single device more versatile.

As shown in Figure 3, any of the compartments may be further provided with elongate fibers or strips 50 that enhance thermal properties by slowing heat transfer. Although discussed primarily for treatment of the body, device 1 of the invention may be used for heating or cooling any surface.

Instant hot or cold disposable packs are well known in the art. They are devices that consist of a sealed plastic bag containing separated chemicals such as, for example, a dry chemical with either a positive or a negative heat of solution and a sealed plastic bag of water. Device 1 is activated by bursting the separating partition or inner bag of water and mixing the two ingredients to produce instant heat or cold. In an alternative embodiment of the invention, the removable inner pouch 24 may be one of these instant hot or cold packs.

Although discussed primarily for treatment of the body, device 1 of the invention may be used for heating or cooling any surface.

Instant hot or cold disposable packs are well known in the art. They are devices that consist of a sealed plastic bag containing separated chemicals such as, for example, a dry chemical with either a positive or a negative heat of solution and a sealed plastic bag of water. Device 1 is activated by bursting the separating partition or inner bag of water and mixing the two ingredients to produce instant heat or cold. In an alternative embodiment of the invention, the removable inner pouch 24 may be comprised of one or more of these instant hot or cold packs.

Referring now to Figs. 8 and 9, the heating or cooling pad or heat transfer device 30 of the invention comprises a flexible outer envelope 42 that can conform to a body part when applied thereto and secured with elongate straps that terminate in hook 44 and loop 45 fasteners. Other fasteners such as snaps, buckles and the like may be used. The envelope 42 is formed of a first sheet or panel 46 and a second sheet or panel 47 that are heat sealed together along all edges 48 to enclose a volume 49. Enclosed within volume 49 is a high thermal capacity first material 53 being, for example, one of the freezing gels well known in the art, such as that disclosed by U.S. Patent 4,324,111 which changes state from liquid to slush at around zero degrees centigrade and requires considerable heat energy as it warms through this change of state to serve as an artificial ice that is not rigid. U.S. Patent 5,314,005 discusses other materials for this purpose including some that may be heated in a microwave oven for use as hot packs.

The envelope is comprised of flexible sheet that is impermeable to the material and is readily conformable to the body part when strapped thereto for effective contact and heat transfer.

5 The thickness of the various sheet materials has been exaggerated for illustrative purposes. Enclosed within the volume 49, and surrounded by first material 53, is a flexible inner pouch 60. The pouch 60 encloses an inner space 62 that is filled with a high thermal capacity second material 55. The webs 61 and 63 from which the pouch 60 is formed is a flexible sheet such  
10 as a plastic heat sealable film that is impervious to the first and second materials so that they cannot mix. The pouch 60 is formed by heat sealing all the edges 66 of two webs 61 and 63 of the plastic film.

Referring now to Figure 10, another embodiment is shown in which the inner pouch 60 is formed from an extruded plastic film  
15 having opposed rounded edges 80. A length of the extruded tube is sealed at one end, filled with second material 55 and then sealed at a second end. At least one of the inner pouch space 62 or the surrounding outer volume 49 may be provided with elongate strips  
20 or fibers 75 to slow heat transfer by reducing convective movement.

The high thermal capacity material 55 in the pouch 60 may be identical to, or different from, the material 53 within the envelope walls. It may even be rigid when frozen such as plain water, since segmentation provides some flexibility.

25 The materials 55 and 53 may be selected on the basis of their particular physical properties to enhance the utility of device 1. Those properties include, but are not limited to, heat of fusion, heat capacity, thermal conductivity, temperature of transition from liquid to solid, rigidity in the solid phase, reaction to microwave  
30 radiation, vapor pressure and boiling point.

Thermal conductivity of the material 53 is important in the rate of transfer of heat to or from the insert or pouch 60. By acting as a partial insulator, it can prolong the cooling effect and also prevent a very cold or hot insert from injuring the skin,  
35 while maintaining a relatively uniform surface temperature.

Referring now to Figure 11, another embodiment of an inner pouch 90 is shown in which the pouch is segmented as shown to make

it more flexible and to maintain a flatter shape by sealing together along seams 97 the outer walls of the pouch.

Referring now to Figs. 12 and 13, another embodiment is shown in which there are a plurality of inner pouches 120 that are not  
5 attached to each other that are contained within the outer envelope 102. Each pouch 120 defines a volume 123 which contains high thermal capacity second material 55 and the pouches are surrounded by high thermal capacity first material 53.

Although discussed primarily for treatment of the body,  
10 device 1 of the invention may be used for heating or cooling any surface.

Instant hot or cold disposable packs are well known in the art. These devices typically comprise a sealed plastic bag containing separated chemicals such as, for example, a dry chemical  
15 with either a positive or a negative heat of solution and a sealed plastic bag of water. Device 1 is activated by bursting the separating partition or inner bag of water and mixing the two ingredients to produce instant heat or cold. In an alternative embodiment of the invention shown in Figure 14, the inner pouch 140  
20 may be one of these instant hot or cold packs.

In this embodiment, water 141 is contained in first chamber 149 hermetically sealed from second chamber 151 by frangible partition 154. Second chamber 151 contains crystals 143  
25 that get hot or cold when dissolved in water due to their heat of solution. When outer envelope 42 is squeezed to cause frangible partition 154 to burst, water dissolves crystals 143 and produces heat or cold.

The invention can include an insulating layer. Insulating layers decrease the rate at which heat is transferred from  
30 device 1. The insulating layer creates two effects. First, device 1 transfers heat for a longer period of time because heat transfer is impeded by the insulating layer. Second, if the heat transfer of the device is too great, the heat transfer can be reduced by interposing the insulating layer between device 1 and the surface  
35 with which heat is being transferred.

As shown in Figures 15-16, one embodiment includes air bladder 204. Air bladder 204 is formed by attaching bladder wall 201 to envelope 2. Bladder wall 201 has perimeter 202 around

its edge. By attaching perimeter 202 to envelope 2, air bladder 204 is defined. Preferably, the attachment of perimeter 202 to envelope 2 is air tight. Air bladder 204 is typically filled with air; however, other insulators can be included. Preferably, bladder wall 201 includes valve 203. Valve 203 when opened allows air to enter or exit air bladder 204. Valve 203 when closed seals air bladder 204. Preferably, bladder wall 201 overlays envelope 2.

As shown in Figure 16, device 1 can include more than one air bladder 204 and 204'. By including more than one air bladder 204 and 204', the inflation of each bladder can be controlled. By changing inflation, the insulating and cushioning effect of air bladders 204 and 204' can be changed.

As shown in Figures 17-18, the invention includes an embodiment having insulator 210. Insulator 210 is a layer of material having a high thermal capacity. Insulator 210 may be but is not limited to an open-celled foam, a closed-cell foam, down, or batting. By including insulator 210 on at least one side of envelope 2, the heat being transferred through the side having insulator 210 is minimized. To utilize this property, insulator 210 is placed against the surface with which heat is being transferred if too much heat is being transferred by device 1. Conversely, if too little heat is being transferred by device 1, insulator 210 is placed away from the surface with which heat is being transferred in order to prevent heat from being inefficiently lost from the side of device 1 that is not in contact with the surface.

Insulator 210 can be used to promote wet therapy. By providing a water-absorbent insulator 210, insulator 210 can hold water. This water becomes heated by device 1.

Insulator 210 can be made of a sanitized material. By being sanitized the risk of infection is minimized. Examples of sanitary insulators 210 include but are not limited to laminate polyester, cloth, neoprene, and nylon. The invention also encompasses embodiments wherein insulator 210 is removable. Removable sanitized insulators 210 allow the device to be reused with clean insulators 210 for each patient.

A hot or cold bandage can be constructed according to the invention. In one embodiment, device 1 is covered by adhesive strip 220 having adhesive side 221 that adheres to device 1 and the surface with which heat is to be transferred. Adhesive strip 220 holds the hot or cold pad against the surface and frees a user from having to hold device 1 in place.

Figures 19 and 20 show a hot or cold bandage 230 which contains a pad made from a plurality of sheets. First sheet 231, second sheet 232, and third sheet 233 are preferably congruent so each has a similar perimeter 234, 235, and 236, of each respectively, is substantially in registry with the others. By stacking sheets 231, 232, and 233 and joining them at their respective perimeters 234, 235, and 236, two cavities 237 and 238 are defined between sheets 231, 232, and 233. First cavity 237 is then filled with high thermal capacity first material 11 and second cavity 238 is then filled with high thermal capacity second material 12. Alternatively, adhesive strip 220 having adhesive side 221 is then placed over the sheets with adhesive side 221 facing sheets 231, 232, and 233. Adhesive strip 220 is larger than sheets 231, 232, and 233 and therefore extends beyond them. Adhesive side 221 is then attached to the surface with which heat is to be transferred. Adhesive strip 220 thereby holds bandage 230 on the surface.

In its preferred form, bandage 230 includes additional layers. Fourth sheet 239 having perimeter 240 can be attached to either exterior sheet, first sheet 231 or third sheet 233, by stacking fourth sheet 239 with the other sheets and attaching perimeter 240 to define air cavity 241. Air cavity 241 contains air or another suitable insulator. Air cavity 241 not only acts as an insulator but also as a cushion. In its most preferred embodiment, fourth sheet 239 is distal adhesive strip 220. Air cavity 241 acts as a cushion and an insulator that controls heat transfer.

In its preferred form, bandage 230 includes insulator 210. As stated insulator 210 includes but is not limited to an open-celled foam, a closed-cell foam, down, gauze, and batting. In its most preferred form, insulator 210 is proximate adhesive strip 220 relative to sheets 231, 232, and 239.



As shown in Figure 21, an embodiment of device 1 includes a plurality of holes 250 which can be used in conjunction with belt 251 to attach device 1 to a surface. Holes 250 are located in envelope 2. While holes 250 go through envelope 2, envelope 2 remains sealed about holes 250. Belt 251 can be threaded through holes 250. Belt 251 is then wrapped around a surface with which device 1 is to exchange heat.

As shown in Figure 22, in situations where the duration of heat exchange is to be extended, device 1 is preferred to have a cylindrical shape. By being cylindrically shaped, the surface-to-volume ratio for a given length is minimized. By minimizing the ratio, the heat transfer which depends directly on surface area is minimized while the volume of heated or cooled material is maximized.

As shown in Figures 23 and 24, a hot or cold pad 263 having a plurality of connected envelopes 2 is encompassed by another embodiment of the invention. In this embodiment, a plurality of pads are connected in series. Each pad may be characterized in a manner similar to any of the hot or cold pads described above in that it has an envelope 2 containing first material 11, and a pouch containing second material 12 within envelope 2. Web 260 connects envelope 2 to adjacent envelopes 2'. A plurality of webs 260 are included in order to connect each envelope 2 to its adjacent envelopes 2', preferably, by a single web 260. In a preferred form, webs 260 include passageway 261. Passageway 261 allows first material 11 to flow from envelope 2 to adjacent envelope 2'. Preferably, webs 260 are thinner than envelope 2. And, by being thin, webs 260 act as hinges allowing pad 263 to be flexible and contoured to the surface with which heat is to be transferred.

The invention also encompasses an embodiment that is microwavable. To guarantee that the envelope 2 does not burst during normal microwave heating, wall 270 of envelope 2 should be at least five millimeters (5 mm) thick.

The invention also encompasses an embodiment that minimizes the risk of poison. In this embodiment, material 11 preferably comprises a food grade gelatin. Similarly, material 12 may also comprise a food grade gelatin.

The invention also encompasses embodiments that are shaped like the surface with which heat is to be transferred. For example, device 1 can be shaped like shoe 280 for use on a foot, or like sock 281 for use on an ankle, or mask 282 for use on the face, or cap 283 for use on the head, or cuff 284 for use on the neck, lumbar pad 284 for use on the lumbar region of the back, or belt 285 for use on the waist. Device 1 also can be shaped like inanimate objects, such as plate 286, bowl 287, and cup 288. By being so shaped, contact between device 1 and the surface with which heat is being transferred is improved.

The above disclosed invention has a number of particular features which should preferably be employed in combination although each is useful separately without departure from the scope of the invention. While this section shows and describes the preferred embodiments have been shown of the invention, the invention may be embodied other than as herein specifically illustrated or described, and that certain changes in the form and arrangement of parts and the specific manner of practicing the invention may be made within the underlying idea or principles of the invention.

#### INDUSTRIAL APPLICABILITY

The industrial applicability can be understood by analyzing the objects of the invention and the problems that are solved by accomplishing these objects.

It is accordingly an object of the invention to provide a cooling and/or heating applicator that is sufficiently flexible to conform to various body parts to make surface contact for effective heat transfer.

It is another object that the applicator provide heating and/or cooling at an effective temperature for a greatly prolonged period of time for optimal therapeutic benefit.

It is another object that the device, in one embodiment, be reversible so that the surface properties may be altered in at least one alternative embodiment.

It is yet another object that the device, in one embodiment, have a removable inner portion that may be separately heated or cooled in an alternative embodiment of the invention.

Another object of the present invention is to provide a series of such hot or cold packs which are specifically designed to be conveniently and efficiently applied to parts of the anatomy such as the lumbar back region, the wrist, the knee or elbow, the cervical back region, i.e. the neck and upper back, the foot, the face, the leg, the pelvis, etc.

Yet another object of the present invention is to provide a hot or cold pack, or series of such hot or cold packs, which cause heat transfer with any body, animate or inanimate.

A still further object of this invention is to provide a hot or cold applicator for facilitating heat transfer with a body or body part in the form of such well known articles as gloves, socks, hoods, belts, or any other suitable clothing article.

It is also an object of this invention is to provide a hot or cold applicator which is combined with material for bandaging wounds.

It is also an object of this invention to provide a hot or cold applicator having an outer layer thereof at least a portion of which is capable of absorbing and holding liquid such as water to provide moist heat to a surface when the applicator is at an elevated temperature.

It is a further object of this invention to provide a hot or cold applicator having means thereon for connecting and/or holding such applicator to a surface to or from which heat is transferred from or to the applicator.

It is also an object of this invention to provide a hot or cold applicator for use in connection with forming or cooling articles of food and/or beverages.

## CLAIMS:

I claim:

1. A heating or cooling pad comprising:

5 an outer, flexible, sealed, envelope containing a high thermal capacity first material, said envelope being impervious to said first material;

10 at least one inner pouch also contained within said envelope, said pouch comprising a high thermal capacity second material sealed within an enclosing web that is impervious to said second material, so that said first and second materials cannot mix; [and]

said first material being non-rigid at about zero degrees centigrade; and

15 means associated with said outer envelope and inner pouch for retaining said inner pouch in position relative to said outer envelope.

20 2. The heating or cooling pad according to claim 1, in which said second material is non-rigid at zero degrees centigrade.

3. The heating or cooling pad according to claim 2, in which said first and second materials have different physical properties.

25 4. The heating or cooling pad according to claim 1, in which said first and second materials have different physical properties.

5. The heating or cooling pad according to claim 1, in which said at least one inner pouch is segmented.

30 6. The heating or cooling pad according to claim 1, in which said enclosing web is formed of a flexible extruded web having two opposed rounded edges.

35 7. The heating or cooling pad according to claim 1, in which elongate fibers are provided within at least one of said first and second material.

8. The heating or cooling pad according to claim 1, in which elongated strips are provided in at least one of said first and second material.

5 9. A heat transfer device for heating and cooling a surface, the device comprising:

an envelope formed of first and second sheets, the sheet having broad faces;

10 each sheet formed of an outer panel of flexible, liquid-impermeable webbing, the panels joined together on all edges to define therebetween a volume that contains a high thermal capacity first material that is not rigid at about zero degrees centigrade;

15 the volume further containing therein at least one pouch sealingly enclosing a space, the space containing therein a high thermal capacity second material, the pouch being formed of web that is impermeable to said first and second material so that said first and second materials cannot mix; and

means connecting said pouch to said envelope so that said pouch is substantially fixed relative to said envelope.

20

10. The device according to claim 9, in which said first and second material have different physical properties.

25 11. The device according to claim 9, in which said at least one pouch is segmented.

12. The device according to claim 9, in which said first and second materials have the same physical properties.

30 13. The device according to claim 9, in which said first material is a freezing gel.

14. The device according to claim 9, in which elongate fibers or strips are provided in one or both of the space and the volume.

35

15. The heating or cooling pad of claim 1, wherein said means associated with said outer envelope and inner pouch includes at least one transverse web connected between opposed sides of said

outer envelope and cooperating with at least one corresponding notch defined said inner pouch to retain said pouch in substantially fixed relationship within said envelope.

5 16. The heating or cooling pad of claim 1, wherein said means associated with said outer envelope and inner pouch is a fixed connection between said pouch and said envelope wherein said pouch is fused to said outer envelope.

10 17. The heat transfer device of claim 9, wherein said means connecting said pouch to said envelope includes at least one web rigidly connected at one side to said envelope and at another side to said pouch.

15 18. The heat transfer device of claim 9, wherein said means connecting said pouch to said envelope includes adhering said pouch to said envelope.

20 19. The heat transfer device of claim 9, wherein said means for connecting said pouch to said envelope includes fusing said pouch to said envelope.

20. A heating or cooling pad comprising:

25 an outer, flexible, sealed, envelope containing a high thermal capacity first material, said envelope being impervious to said first material;

30 at least one inner pouch also contained within said envelope, said pouch comprising a high thermal capacity second material sealed within an enclosing web that is impervious to said second material, so that said first and second materials cannot mix, two separate chambers hermetically sealed from each other by a frangible partition and the two chambers containing different materials which, when mixed together after manually breaking said partition, form said high thermal capacity second material and also  
35 produce either heat or cold upon mixing, and

said first material being non-rigid at about zero degrees centigrade.

21. A heat transfer device for heating and cooling a surface, the device comprising:

an envelope formed of first and second sheets, the sheet having broad faces;

5 each sheet formed of an outer panel of flexible, liquid-impermeable webbing, the panels joined together on all edges to define therebetween a volume that contains a high thermal capacity first material that is not rigid at about zero degrees centigrade; and

10 the volume further containing therein at least one pouch sealingly enclosing a space, the space containing therein a high thermal capacity second material, the pouch being formed of web that is impermeable to said first and second material so that said first and second materials cannot mix, two separate chambers  
15 hermetically sealed from one another by a frangible partition and the two chambers contain different parts which, when mixed together after manually rupturing the partition, from said high thermal capacity second material and also generate either heat or cold.

20 22. The heating or cooling pad as described in claim 1, wherein said envelope further comprises:  
two outer faces.

23. The heating or cooling pad as described in claim 22 further comprising:  
25 an insulating layer attached to said envelope.

24. A heating or cooling pad as described in claim 22, wherein said insulating layer comprises:

30 a bladder wall having a perimeter,  
wherein said perimeter attaches to said envelope to define a bladder between said envelope and said bladder wall.

25. A heating or cooling pad as described in claim 24, wherein  
35 said bladder is air sealed.

26. A heating or cooling pad as described in claim 25 wherein said insulating layer further comprises:

a valve in said bladder the when opened allows said bladder to be inflated and deflated and when closed seals said bladder.

27. A heating or cooling pad as described in claim 23, wherein  
5 said insulating layer comprises an insulator.

28. A heating or cooling pad as described in claim 27, wherein  
said insulator is chosen from the group consisting of an open-  
celled foam, a closed-cell foam, down, and batting.

10

29. A heating or cooling pad as described in claim 23 wherein said  
insulating layer comprises:

a bladder wall having a perimeter, wherein said perimeter  
attaches to a first of said outer faces to define a bladder between  
15 said first of said faces and said bladder wall.

30. A heating or cooling pad as described in claim 29, further  
comprising:

a second bladder wall having a second perimeter, wherein said  
20 second perimeter attaches to a second of said outer faces to define  
a second bladder between said second bladder wall and said second  
face.

31. A heating or cooling pad as described in claim 29, wherein an  
25 insulator covers a second of said outer faces.

32. A heating or cooling pad as described in claim 31, wherein  
said insulator is chosen from the group consisting of an open-  
celled foam, a closed-cell foam, down, and batting.

30

33. The heating or cooling pad as described in claim 1 further  
comprising:

a bandage having an adhesive side that adheres to said pad and  
a surface.

35

34. A heating or cooling bandage comprising:  
a first sheet having a perimeter,



a second sheet having a perimeter, wherein said second sheet is substantially in registry with said first sheet, and wherein said first sheet and said second sheet are stacked and joined at said perimeters to define a first cavity between said first sheet and said second sheet,

a third sheet having a perimeter, wherein said third sheet is substantially in registry with said second sheet, and wherein said third sheet and said second sheet are stacked and joined at said perimeters to define a second cavity between said first sheet and said second sheet,

a first high thermal capacity material in said first cavity  
a second high thermal capacity material in said second cavity,  
and

an adhesive strip having an adhesive side, wherein said adhesive strip at least partially overlaps said first sheet, and wherein said adhesive side faces said first sheet.

35. A hot or cold bandage as described in claim 34 further comprising:

a fourth sheet having a perimeter, wherein said fourth sheet is substantially in registry with said third sheet, and wherein said fourth sheet is stacked on said third sheet and joined at said perimeters to define an air cavity.

36. A hot or cold bandage as described in claim 34 further comprising:

an insulator located between said first sheet and said adhesive strip.

37. A hot or cold pad as described in claim 1, wherein said envelope contains at least two holes that are sealed so said high thermal capacity first material cannot exit said holes.

38. A hot or cold pad as described in claim 37 further comprising:  
a belt threaded through said holes.

39. A hot or cold pad as described in claim 1, wherein said envelope is cylindrically shaped.

40. A hot or cold pad as described in claim 1, further comprising:  
a plurality of said envelopes, each containing at least one  
of said inner pouches, wherein said envelopes are arranged in  
series so that each of said envelopes has at least one adjacent  
5 envelope but no more than two adjacent envelopes, and

a plurality of webs, wherein said webs connect each envelope  
to its respective adjacent envelopes.

41. A hot or cold pad as described in claim 40, wherein said webs  
10 each define a passage that allows said high thermal capacity first  
material to pass from one of said envelopes to said adjacent  
envelopes.

42. A hot or cold pad as described in claim 1, wherein said  
15 envelope has a wall that is at least five millimeters (5 mm) thick.

43. A hot or cold pad as described in claim 1, wherein said  
envelope has a shape chosen from the group consisting of a lumbar  
region, a wrist, a knee, an elbow, a cervical region, a neck, a  
20 foot, a face, a mask, a belt, a hat, a jacket, a bowl, and a cup.

44. A hot or cold pad as described in claim 1, wherein said high  
thermal capacity first material comprises a food grade gelatin.

45. A hot or cold pad as described in claim 1, wherein said high  
25 thermal capacity second material comprises a food grade gelatin.

46. The heating or cooling pad as described in claim 23, wherein  
said insulating layer is water absorbent.

47. The heating or cooling pad as described in claim 23, wherein  
30 said insulating layer is sanitized.

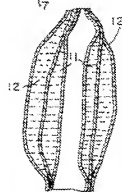
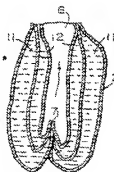
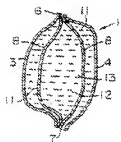
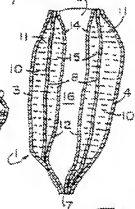
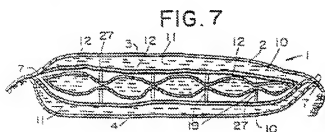
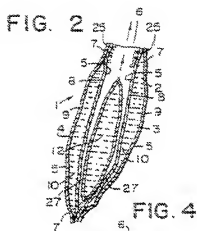
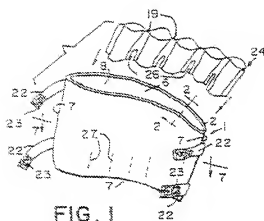
48. The heating or cooling pad as described in claim 23, wherein  
35 said insulating layer is removable.

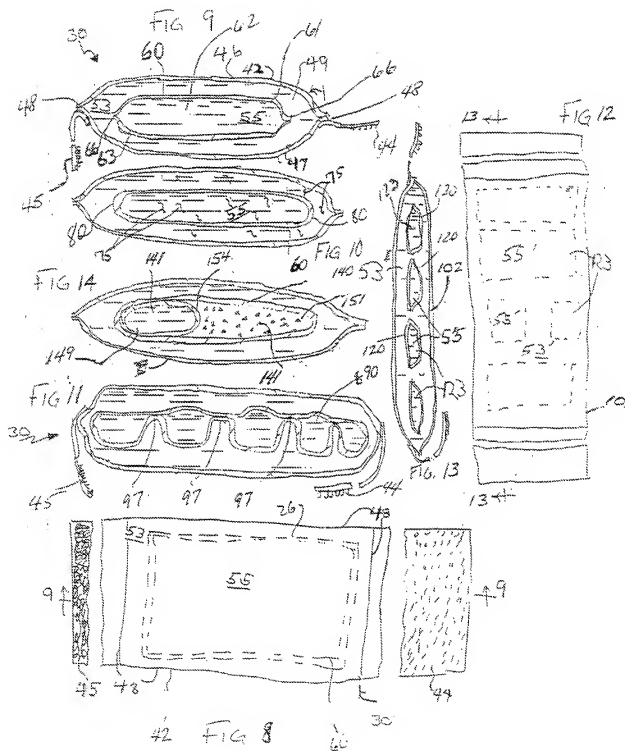
49. The heating or cooling pad as described in claim 1, wherein  
at least one of said materials is chosen from the group consisting

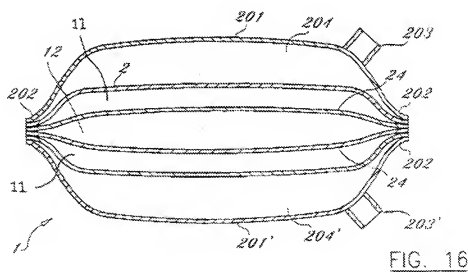
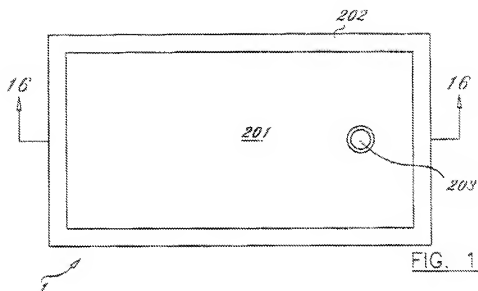
of water, propylene glycol, hydroxypropyl methylcellulose, natural gum, cellulosic polymer, animal polymer, gelatin, guar gum, gum tragacanth, locust bean gum, Xanthan gum, cellulose, lignocellulose, hydroxymethyl cellulose, acrylic acid, methacrylic acid, a wetting agent, and a freezing point depressant.

50. The heating or cooling pad as described in claim 49, wherein said wetting agent is chosen from the group consisting of alcohols, ethylene glycol, propylene glycol, glycerine, methanol, ethanol, and propanol.

51. The heating or cooling pad as described in claim 49, wherein said freezing point depressant is chosen from the group consisting of monohydric alcohol, monohydric alcohol derivate, ethylene glycol, propylene glycol, 1,3-propylene glycol, glycerin, 2-methyl-2,4-pentanediol, acetone, dimethylsulfoxide, methylsulfonic acid, ethylsulfonic acid, diethylamine, methylamine, formic acid, erythritol, arabinose, gluconic acid, glucuronic acid, glucaric acid, galacturonic acid, fructose, glucosamine, disaccharides, raffinose, agarose, amylose, sodium alginate, glycogen, chondroitin, chondroitin sulfuric acid, dextran, pectic acid, propylene glycol alginate, pullulan, and chondroitin sodium sulfate.







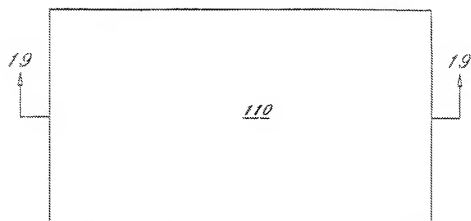


FIG. 17

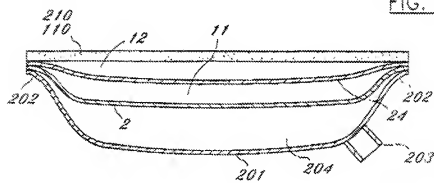


FIG. 18

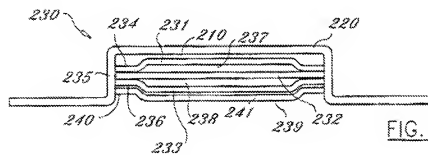


FIG. 19

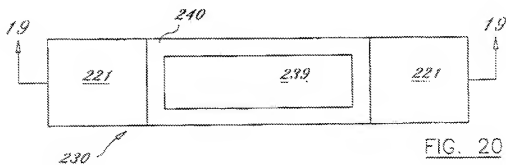


FIG. 20

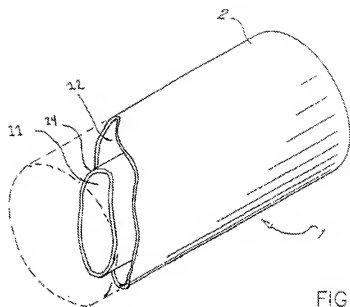


FIG. 22

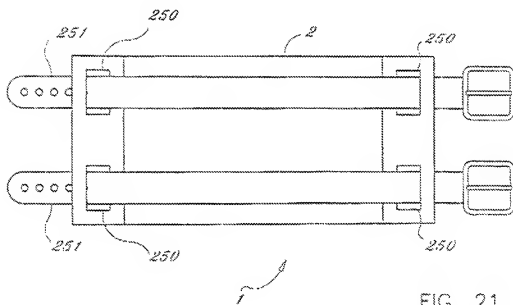


FIG. 21



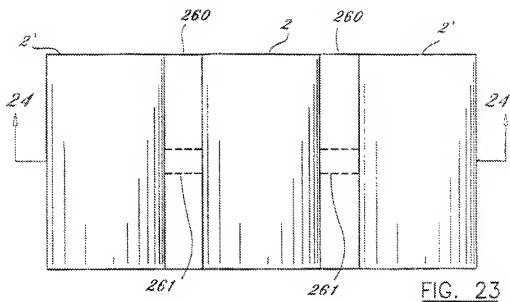


FIG. 23

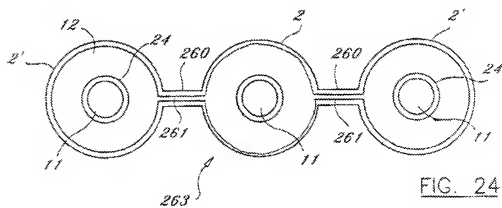


FIG. 24

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/16251

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61P 7/00

US CL : 62/530; 607/96, 112, 114

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 62/530; 126/204; 165/46; 383/901; 607/96, 112, 114

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,069,208 A (NOPPEL et al) 03 December 1991, Fig. 1, and cols. 2-4.	1-4, 6 ----- 33, 37, 38
X --- Y	US 5,486,206 A (AVERY) 23 January 1996, entire document.	1-14, 17 ----- 16, 18, 19, 34-39, 42-45, 49-51
A	US 5,179,944 A (McSYMYTZ) 19 January 1993, entire document.	1-51
A	US 4,962,761 A (GOLDEN) 16 October 1990, entire document.	1-51

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"P" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"T" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"G" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 26 AUGUST 1999	Date of mailing of the international search report 05 NOV 1999
Name and mailing address of the ISA/US Commissioners of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DAVID RUDDY Telephone No. (703) 308-3595

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US99/16251

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,951,127 A (WATSON et al) 20 April 1976, entire document.	1-51
A	US 5,314,005 A (DOBRY) 24 May 1994, entire document.	1-51